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| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|---------------|-------------|-----------------------|---------------------|
| 08/259,413    | 06/14/94    | HARRIS                | J SYNE210C          |

M. PAUL BARKER, ESQ.  
FINNNEGAN, HENDERSON, FARABOW, GARRETT  
AND DUNNER, LLP  
1300 I STREET, N.W.  
WASHINGTON DC 20005-3315

HM31/0601

| EXAMINER     |              |
|--------------|--------------|
| LILLING, H   |              |
| ART UNIT     | PAPER NUMBER |
| 1651         | #13          |
| DATE MAILED: | 06/01/98     |

**Please find below a communication from the EXAMINER in charge of this application.**

Commissioner of Patents



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|                            |             |                       | EXAMINER         |
| HM31/0601                  |             |                       | LILLTING, H      |
|                            |             |                       | ART UNIT         |
| THERESA A BROWN            |             |                       | PAPER NUMBER     |
| INTELLECTUAL PROPERTY DEPT |             |                       |                  |
| SYNERGEN INC               |             |                       |                  |
| 1885 33RD STREET           |             |                       | 1651             |
| BOULDER CO 80301           |             |                       | II               |
| DATE MAILED: 06/01/98      |             |                       |                  |

This is a communication from the examiner in charge of your application.  
**COMMISSIONER OF PATENTS AND TRADEMARKS**

## OFFICE ACTION SUMMARY

Responsive to communication(s) filed on OCT 23, 1996

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### **Disposition of Claims**

|   |   |
|---|---|
| <input checked="" type="checkbox"/> Claim(s) <u>1-14</u>          | is/are pending in the application.                  |
| <input type="checkbox"/> Of the above, claim(s) <u>1-14 34-43</u> | is/are withdrawn from consideration.                |
| <input type="checkbox"/> Claim(s) _____                           | is/are allowed.                                     |
| <input checked="" type="checkbox"/> Claim(s) <u>15-53 44</u>      | is/are rejected.                                    |
| <input type="checkbox"/> Claim(s) _____                           | is/are objected to.                                 |
| <input checked="" type="checkbox"/> Claim(s) <u>1-4 49</u>        | are subject to restriction or election requirement. |

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received:

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**-SEE OFFICE ACTION ON THE FOLLOWING PAGES-**

Se V 3 08 | 259413

15. Receipt is acknowledged of the election with traverse filed October 23, 1996.

16. The restriction is proper according to the MPEP under 35  
5 U.S.C. § 121 as stated in the previous Office action. Applicant  
has elected with traverse, Group III, Claims 15-33 and 44, drawn  
to substantially purified compounds of  $R_1$ -X- $R_2$  and pharmaceutical  
composition containing the compounds, classified in numerous  
Classes and subclasses based on non-peptidic polymer and  $R$ 's  
10 groupings.

The arguments have been deemed not to be persuasive to withdraw the restriction requirement. The search and examination for the claimed invention as well as the additional inventions would require an exceptional burden on this Examiner in view of the  
15 Office requirement to have compact prosecution. The election of species is appropriate unless Applicant states on the record that all species are obvious over each other as recited in the previous Office action:

20 Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either  
25 instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Claims 1-14 and 34-43 are thusly withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention(s), the requirement having been traversed in Paper No. 7.

5 The restriction and election requirement for the non-elected claims will be reconsidered upon the allowance of any generic claims which does not require any additional undue burden for the examination of the non-elected claims.

10 17. Claims 15-33 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 The language of the claims must make it clear what subject matter the claims encompass for the "metes and bounds", see the following decisions: In re Hammack, 427 F2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F.2d 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357 1366, 178 USPQ 486, 492 (CCPA 1973).  
20 The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover, see e.g. In re Steele, 305 F. 2d 859, 134 USPQ 292 (CCPA 1962); In re Moore 439 F.2d 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F.2d 1390, 186 USPQ 471 (CCPA 1975). The former decision indicated that if upon analysis the claims were found to be indefinite under the second paragraph of 35 USC 112, they could not even be analyzed under the first paragraph 25 of 35 USC 112 because that analysis of the claims could not be carried out unless one was able to determine what the claimed subject matter encompassed for the examiner to consider.  
30

What is the scope of X?

What is scope of  $R_2$ ? Does it include any and all compounds that reacts with the polymer?

5 What is the scope of the "second reactive group?

What is the bonding of the "  $R_2$ " with the second reactive group?

10 18. Claims 15-33 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the elected species drawn to the enabling examples, does not reasonably provide enablement for broad functional claimed language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, see In re Fisher, 166 USPQ 18, 24 (June 11 1970):

20 Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved,

The claims are considered to be unreasonable in view of enabling specification.

5 19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

10 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 17-19, 22, 31-33 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shaw et al U.S. 5,166,322, see column 15-16 examples in particular which are considered to be within the 20 scope of the broad claimed invention(s).

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier 25 communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1808) is (703) 308-0294 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

30 H.J.Lilling: HJL  
(703) 308-2034  
Art Unit 1808  
June 23, 1997



HERBERT J. LILLING  
PATENT EXAMINER  
GROUP 150 - ART UNIT 1808